## **REMARKS**

The specification has been amended to insert priority data on page 1 in accordance with 37 C.F.R. § 1.78(a)(5).

Claims 1-55 are pending in this application.

## THE RESTRICTION REQUIREMENT

#### A. Election/Restrictions

The Examiner has required restriction of the claims under 35 U.S.C. § 121 to one of the following groups of claims:

- 1. Claims 1-7 (in part), drawn to methods of screening or identifying a subject at risk of developing Vascular Response, classified in class 435, subclass 6.
- 2. Claims 1-7 (in part), drawn to methods of monitoring the effects of therapy administered in a subject, classified in class 435, subclass 4.
- 3. Claims 8-12 and 47-49 (in part), drawn to methods of screening or identifying a subject at risk of developing Vascular Response using proteins, classified in class 435, subclass 7.1.
- 4. Claims 8-12 and 47-49 (in part), drawn to methods of monitoring the effects of therapy administered in a subject using proteins, classified in class 435, subclass 4.
- 5. Claims 13-16, drawn to proteins and kits comprising said proteins, classified in class 530, subclass 350.
- 6. Claims 17-23, drawn to antibodies and kits comprising said antibodies, classified in class 530, subclass 387.1.
- 7. Claim 24, drawn to methods of treating Vascular Response using a protein, classified in class 514, subclass 2.
- 8. Claim 25, drawn to methods of treating Vascular Response using an antibody, classified in class 514, subclass 1.
- 9. Claims 26-28, drawn to methods of treating Vascular Response using a nucleic acid, classified in class 514, subclass 44.

- Claims 29-31 and 43, drawn to methods of screening for agents that interact with a polypeptide, classification undeterminable; classification dependent on agent.
- 11. Claims 32-42, 44-46, 50 and 55, drawn to methods of screening agents that modulate expression or activity of a VRPI, classified in class 435, subclass 4.
- 12. Claims 51-53, drawn to an agent that modulates activity, classification undeterminable; classification dependent on agent.
- 13. Claim 54, drawn to a method of treating or preventing comprising administering an agent that modulates activity, classified in classification undeterminable; classification dependent on agent.

In order to be fully responsive, Applicants hereby provisionally elect with traversal the invention of Group 3, claims 8-12 and 47-49 (in part), drawn to methods of screening or identifying a subject at risk of developing Vascular Response using proteins.

Group 3 is directed to methods of screening or identifying a subject at risk of developing Vascular Response, and Group 4 is directed to methods of monitoring the effects of therapy administered to a subject having Vascular Response. Both Groups 3 and 4 are directed to methods that quantitatively detect Vascular Response-Associated Protein Isoforms (VPRIs) in a sample from the subject. Moreover, both Groups 3 and 4 are classified in class 435. Even assuming arguendo that Groups 3 and 4 represent distinct or independent inventions, Applicants submit that the same subject matter would have to be searched for both of these Groups and thus combining them would not be a serious burden on the Examiner.

Group 1 is directed to methods of screening or identifying a subject at risk of developing Vascular Response, and Group 2 is directed to methods of monitoring the effects of therapy administered to a subject having Vascular Response. Both Groups 1 and 2 are directed to methods that use two dimensional electrophoresis to analyze a test sample of a body fluid or tissue from the subject. Moreover, both Groups 1 and 2 are classified in class 435. Even assuming arguendo that Groups 1 and 2 represent distinct or independent inventions, Applicants submit that the same subject matter would have to be searched for

both of these Groups and thus combining them would not be a serious burden on the Examiner.

Group 5 is directed to VPRIs, and Group 6 is directed to antibodies capable of immunospecific binding to the VPRIs of Group 5. Both Groups 5 and 6 are classified in class 530. Even assuming arguendo that Groups 5 and 6 represent distinct or independent inventions, Applicants submit that the same subject matter would have to be searched for both of these Groups and thus combining them would not be a serious burden on the Examiner.

Groups 7-9 are directed to methods of treating a subject having Vascular Response by administering to the subject a VPRI, an antibody capable of immunospecifically binding to a VPRI, and a nucleic acid encoding a VPRI, respectively. Groups 7-9 are all classified in class 514. Even assuming arguendo that Groups 7-9 represent distinct or independent inventions, Applicants submit that the same subject matter would have to be searched for both of these Groups and thus combining them would not be a serious burden on the Examiner.

Applicants respectfully direct the Examiner's attention to the Manual of Patent Examining Procedure ("MPEP") (8th edition, 2001), which provides, at section 803:

If the search and examination of an entire application can be made without serious burden, the examiner <u>must</u> examine it on the merits, even though it includes claims to independent or distinct inventions. (emphasis added)

In view of this provision, and the foregoing showing of no serious burden, Applicants respectfully request that the restriction requirement under § 121 be withdrawn in part, for the reasons stated above, and that Groups 3 and 4 be combined and examined together, Groups 1 and 2 be combined and examined together, Groups 5 and 6 be combined and examined together, and Groups 7-9 be combined and examined together.

## B. Further Restriction

The Examiner has further required election of a single Vascular Response Associated Feature, Vascular Response Associated Protein Isoform, or antibody. The Examiner contends that each of the compounds is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Applicants respectfully traverse and would like to direct the Examiner's attention to section 803.02 of the MPEP. According to the MPEP, when presented with a Markush-type claim including independent and distinct inventions, the Examiner may require a <u>provisional election</u> of a single species, as opposed to requiring <u>restriction</u> to a species. Once an Applicant elects a species, section 803.02 of the MPEP states that

the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

Applicants submit that, in accordance with the MPEP<sup>1</sup>, the Examiner should require an election of a single species, rather than require restriction to a species as the Examiner has done in the outstanding Office Action.

Should Applicants' foregoing argument be deemed persuasive by the Examiner, Applicants hereby <u>provisionally</u> elect the species VRPI-1.

However, in order to be fully responsive to the species restriction requirement, Applicants hereby elect, with traversal, a single Vascular Response-Associated Protein Isoform, namely VRPI-1, and its corresponding Vascular Response-Associated Feature, namely VRF-1. Applicants fully reserve their rights to prosecute the non-elected subject matter in one or more related applications.

<sup>&</sup>lt;sup>1</sup> "Election of species should be required prior to search on the merits . . . in all applications containing both species claims and generic or Markush claims." See MPEP section 808.01(a).

# **CONCLUSION**

Applicants reserve the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully request that the above remarks be entered and made of record in the file history of the instant application.

Respectfully submitted,

Date: March 15, 2004

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